APR 2 7 2004

K040632

Smiths Medical ASD, Inc.
160 Weymouth Street
Rockland, MA 02370

Regulatory Submission Summary
510(k) Summary of Safety and Effectiveness

The 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

SUBMITTER NAME:	Smiths Medical ASD, Inc.
SUBMITTER ADDRESS:	160 Weymouth Rockland MA 02370
CONTACT PERSON:	Vernon Trimble Director of Regulatory Affairs/Quality Assurance
PHONE NUMBER:	781-878-8011
FAX NUMBER:	781-878-7540
SUMMARY DATE:	March 9, 2004
DEVICE TRADE NAME:	Sterile Cardiac Blanket (a component of Snuggle Warm® 4000 Convective Warming System)
COMMON NAME:	Convective Warming Blanket (a component of Convective Warming System).
DEVICE CLASSIFICATION NAME:	The FDA has classified Thermal Regulation Systems as Class II devices under CFR Title 21, Section 870.5900. The product code is DWJ.
PREDICATE DEVICE:	Snuggle Warm® 4000 Convective Warming System that includes non-sterile Convective Warming Blankets (Model SW4000)
DEVICE DESCRIPTION:	The Snuggle Warm® 4000 Convective Warming System consists of a Convective Warming Unit, a hose that connects to the Convective Warming Unit on one end and connects to a blanket on the other end. The forced warm air travels from the Warming unit through the hose to the blanket that is placed on the patient.
INDICATIONS FOR USE:	The device is intended for thermal regulating a patient's temperature to prevent hypothermia by a warm air heated blanket to reduce cold discomfort during and after surgical procedures.
TECHNOLOGICAL CHARACTERISTICS:	The proposed device has the same technological characteristics (i.e., design, material, chemical composition)as the predicate

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SUMMARY OF PERFORMANCE TESTING:

- **Maximum Temperature delivered to the patient:**
  The Sterile Cardiac Blanket was tested in accordance to the ASTM F 2196-02 Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices. This testing verified that the Sterile Cardiac Blanket maintained a maximum contact surface temperature of not exceeding 48.0°C and an average contact surface temperature of not exceeding 46.0°C in normal condition.

- **Burst Pressure-Pre/post sterilization:**
  The Burst Pressure of the Sterile Cardiac Blanket was tested in the same manner as the currently marketed non-sterile Convective Warming Blankets. The blankets were inflated until bursting, and the burst pressure was measured. The Sterile Cardiac Blanket met the same robustness requirements, as do the predicate blankets.

- **Tape Strength-Pre and Post Sterilization:**
  The tensile strength of the tape bond was measured pre and post sterilization, and after 3 levels of ethylene oxide exposure. While 3 levels of ethylene oxide dosage would represent a worst-case scenario. Test results indicate that sterilization have minimal negative effects on the tape adhesive.

CONCLUSION:

The Sterile Cardiac Blanket performs as intended according to its performance specifications. The Sterile Cardiac Blanket is ***substantially equivalent*** to the predicate device (that includes non-sterile blankets). The Sterile Cardiac Blanket is ***substantially equivalent*** to the non-sterile blanket with respect to the intended use as a component of the Snuggle Warm® 4000 Convective Warming System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2004

Smiths Medical ASD, Inc.
c/o Mr. Vernon Trimble
Director of Regulatory/Affairs/Quality Assurance
160 Weymouth Street
Rockland, MA 02370

Re: K040632
Snuggle Warm 4000 Convective Warming System, Model SW4000
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulatory System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: March 31, 2004
Received: April 2, 2004

Dear Mr. Trimble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040632

Device Name: Sterile Cardiac Blanket

Indications For Use: The device is intended for thermal regulating a patient's temperature to prevent hypothermia by a warm air heated blanket to reduce cold discomfort during and after surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mc Nutt

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040632